REMARKS

At the time the current Official Action was mailed, the Examiner rejected claims 1-13.

Reconsideration of the application in view of the remarks set forth below is respectfully

requested.

Rejections under 35. U.S.C. § 102

The Examiner rejected claims 1, 5, 8, 10, and 11 under 35 U.S.C. § 102 as being

anticipated by the Diab reference (US Patent Application Publication 2002/0128544).

Specifically, the Examiner stated:

> Regarding claim 1, Diab discloses a method comprising using a first and a
> second method to determine the first and second heart rates from a pulse oximetry
> signal (paragraphs [0028], [0257], [0327]), evaluating the reliability of the first
> heart rate using metrics (paragraph [0322]-High Confidence Test Module 301),
> and using the first heart rate when the metrics indicate that the first method is
> reliable and using the second heart rate when the metrics indicate that the first
> method is unreliable (paragraphs [0328]-[0332], [0345]-[0347]-that is, the results
> of the confidence test is used to determine which method of signal processing is
> used to find the heart rate.

> Regarding claim 5, Diab discloses a pulse oximeter that can be used to
> determine a heart rate (paragraphs [0019]-[0020], [0028]) comprising first and
> second heart rate calculators for determining first and second heart rates from a
> pulse oximetry signal using first (element 586) and second (element 590) methods
> (paragraphs [0257], [0327]-[0332]), an evaluator configured to determine the
> reliability of the first heart rate by applying metrics to the first method (High
> Confidence Test Module 301- paragraph [0322]), and a selector configured to use
> the first heart rate when the metrics indicate that the first method is reliable and
> the second heart rate when the metrics indicate that the first method is unreliable.

> Regarding claims 8 and 10, Diab discloses a pulse oximetry system
> comprising a sensor adapted to provide a signal related to a physiological
> constituent (element 300; paragraphs [0019]-[0020], [0028]) and a monitor
> adapted to process the signal to determine a pulse period, the monitor comprising
> software adapted to process the signal to determine a first pulse period using a
> first method (element 586), software adapted to process the signal to determine a

second pulse period using a second method (element 590), an evaluator configured to determine the reliability of the first heart rate by applying metrics to the first method (element 301),and a selector configured to use the first heart rate when the metrics indicate that the first method is reliable and the second heart rate when the metrics indicate that the first method is unreliable (paragraphs [0327]-[0332], [0345]-[0347]). Diab's method converts a frequency spectrum, or pulse period, to a pulse rate.

Regarding claim 11, Diab discloses method of determining a heart rate in a pulse oximeter (element 300; paragraphs [0019]-[0020], [0028]) comprising determining a first pulse period from a pulse oximetry signal using a first method (element 586) and second pulse period from a pulse oximetry signal using a second method (element 590) when the metrics (element 301) indicate that the first method is unreliable, and converting the first pulse period into a heart rate when the metrics indicate that it is reliable and converting the second pulse period into a heart rate when the metrics indicate that the first is unreliable (paragraphs [0327]-[0332], [0345]-[0347]).

The Applicant respectfully traverses this rejection. Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under Section 102, a single reference must teach each and every element or step of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Thus, if the claims recite even one element not found in the cited reference, the reference does not anticipate the claimed invention.

The Diab reference fails to recite the claimed element in claims 1, 5, 8, 10, and 11 of a second method of determining a heart rate. The Examiner has pointed to elements 586 and 590 of the Diab reference as examples of first and second methods of determining a heart rate. The

Examiner is correct that element 590 represents a spectral analysis module that outputs the initial

heart rate determination. However, element 586 in the Diab reference does *not* represent a heart

rate determination method. As shown in Fig. 20 of the Diab reference, there are two possible

inputs to the spectral analysis module 590. A choice is made whether to use input 586 or input

588 based on the presence or absence of detected motion. These inputs represent a spectrum

containing potential peaks *from which no heart rate has yet been determined*. Regardless of the

choice of the spectral estimation input 586 or 588, the spectral analysis module 590 will perform

one method of heart rate determination on the single selected input. Accordingly, the Diab

reference does not disclose a second method of determining a heart rate.

The Diab reference also does not include a selector for choosing between a first heart rate

and a second heart rate as claimed in claims 5, 8, and 10. Because the spectrum analysis module

590 only calculates a single heart rate and does *not* calculate a second heart rate, the Diab

reference does not disclose a selector or a selection step for choosing between a first heart rate

and a second heart rate.

Further, the Diab reference fails to disclose an evaluator (claims 5, 8, and 10) and/or an

evaluating step (claims 1 and 11) for determining the reliability of a first heart rate by applying

metrics to the first method. The Examiner has pointed to paragraph [0322] of the Diab reference

as describing an evaluator that determines the reliability of a first heart rate. However, as recited

in paragraph [0322], the High Confidence Test Module (element 570 in paragraph [0322]-not

element 301 as noted by the Examiner) feeds into the oxygen saturation calculation, and not the

heart rate determination module 590. As shown in Fig. 19 of the Diab reference, the output of

the High Confidence Test Module is ultimately fed into the clip and smooth module 566, which

provides the oxygen saturation values. The clip and smooth filter compares each new saturation

value to previous saturation values according to preset parameters. The clip and smooth module

566 evaluates oxygen saturation values, *not* heart rate values. Accordingly, the Examiner is

incorrect in stating that the results of the confidence test of the High Confidence Test Module are

used to determine which method of signal processing is used to find the heart rate because the

confidence test of Diab does not evaluate the reliability of heart rate values.

For at least these reasons, the Diab reference fails to anticipate claims 1, 5, 8, 10, and 11

under 35 U.S.C. § 102(b). Accordingly, The Applicant respectfully request withdrawal of the

anticipation rejection.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 2, 6, and 12 under 35 U.S.C. § 103(a) as being

unpatentable over the Diab reference in view of the Leon reference (US Patent No. 5,365,934);

and claims 3, 4, 7, 9, and 13 as being obvious over the Diab reference in view of the Baker

reference (US Patent Application Publication 2002/0137994). Specifically, the Examiner stated:

> Regarding claim 2, Diab discloses all the elements of the current invention, as
> described above, except for determining that the first heart rate is unreliable after a pulse
> is rejected. Leon discloses a method of using multiple heart rate signals to determine an
> accurate heart rate where a first is considered unreliable after it is rejected, in favor of an
> alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most
> accurate heart rate is obtained.
>
> ...

Regarding claim 6, Diab discloses all the elements of the current invention, as described above, except for the selector for determining that a first heart rate is unreliable when metrics indicate that a pulse is rejected. Leon discloses using multiple heart rate signals when a first heart rate is considered by a selector to be unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained.

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Regarding claim 12, Diab discloses all the elements of the current invention, as described above, except for the selector for determining that a first heart rate is unreliable when metrics indicate that a pulse is rejected. Leon discloses using multiple heart rate signals when a first heart rate is considered by a selector to be unreliable after it is rejected, in favor of an alternate heart rate candidate (column 12, lines 46-52), in order to ensure that the most accurate heart rate is obtained.

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Regarding claim 3, Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a heart rate using an ensemble averaged waveform. Baker teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate.

• • •

Regarding claim 4, Diab discloses all the elements of the current invention, as described above, except for determining the heart rate by determining the pulse period and converting it to a rate. Baker teaches using pulse oximetry to obtain heart rate signals, where the signals are used to determine a pulse period (average of the pleth), which is converted into a heart rate (pulse rate) (paragraph [0057]), in order to accurately monitor the patient.

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Regarding claim 7, Diab discloses all the elements of the current invention, as described above, except for the first heart rate calculator using an ensemble averaged waveform and the second not. Baker teaches using pulse oximetry to obtain heart rate signals where, as part of determining the most accurate heart rate signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate.

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Regarding claim 9, Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a pulse period using an ensemble averaged waveform. Baker teaches using pulse oximetry to obtain pulse period signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate pulse period.

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Regarding claim 11 [sic], Diab discloses all the elements of the current invention, as described above, except for one of the methods of determining a pulse period using an ensemble averaged waveform. Baker teaches using pulse oximetry to obtain pulse period signals where, as part of determining the most accurate pulse period signal, the pulse period of a particular set of signals (that is, an ensemble), may be averaged (paragraph [0057]), in order to determine an accurate heart rate.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

The rejection of claims 2, 3, 4, 6, 7, 9, 12 and 13 under 35 U.S.C. § 103(a) is defective for at least the reasons set forth above with respect to the rejection of claims 1, 5, 8, 10, and 11 under Section 102. Neither the Diab reference nor any of the supporting

references discloses a method or system in which a first and second heart rate may be

determined by a first and second method, whereby an evaluator determines the reliability of

the first heart rate; and whereby the first heart rate is used when it is reliable and the second

heart rate is used when the first heart rate is unreliable. Accordingly, the combination of

Diab with the supporting references cannot render the Applicant's claims obvious.

Therefore, the Applicant respectfully asserts that the rejections of claims 2, 3, 4, 6, 7, 9, 12

and 13 under Section 103 are erroneous and should be withdrawn.

Conclusion

In view of the remarks set forth above, Applicant respectfully requests reconsideration of the Examiner's rejections and allowance of all pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

General Authorization for Extensions of Time

In accordance with 37 C.F.R. § 1.136, Applicant hereby provides a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefor. Furthermore, Applicant authorizes the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 06-1315; Order No. TYHC:0069/FLE.

Respectfully submitted,

Date: <u>August 28, 2007</u>

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